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10/782,287	02/19/2004	Jei-Fu Shaw	70002-104001	4293
69713	7590	07/14/2010		
OCCHIUTI ROHLICEK & TSAO, LLP				EXAMINER
10 FAWCETT STREET				KIM, TAEYOON
CAMBRIDGE, MA 02138			ART UNIT	PAPER NUMBER
			1651	
NOTIFICATION DATE	DELIVERY MODE			
07/14/2010	ELECTRONIC			

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/782,287	<b>Applicant(s)</b> SHAW ET AL.
	<b>Examiner</b> Taeyoon Kim	<b>Art Unit</b> 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 May 2010.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 14-16,18-20,31-36,45,47,48 and 53-56 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 14-16,18-20,31-36,45,47,48 and 53-56 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
     Paper No./Mail Date 5/4/10
- 4) Interview Summary (PTO-413)  
     Paper No./Mail Date: \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's amendment and response filed on 5/4/2010 has been received and entered into the case.

Claims 1-13, 17, 21-30, 37-44, 46 and 49-52 have been canceled, and claims 14-16, 18-20, 31-36, 45, 47, 48 and 53-56 have been considered on the merits. All arguments have been fully considered.

It is noted that the claim rejection under 35 U.S.C. §103 in the previous OA inadvertently omitted claims 53-56. The current claim rejection contains these claims along with the previously indicated claims.

#### ***Information Disclosure Statement***

The information disclosure statement filed 5/4/2010 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. There is no English translation or indication of any concise explanation of the relevance for two Japanese patent applications (JP-9-9986 and JP 2002-17337\*; \* English translation provided appears to be incorrect). It has been placed in the application file, but the information referred to therein has not been considered.

#### ***Response to Amendment***

The declaration under 37 CFR 1.132 filed 5/4/2010 is insufficient to overcome the rejection under 35 U.S.C. §103 as set forth in the last Office action.

The declaration was focused on the rationale why a person skilled in the art would not have been motivated to use the high-maltose syrup disclosed in Shaw et al. as is to grow microorganisms, and the declaration pointed out the nitrogen source provided by vitamin B as argued by the Examiner would be very low and a person of ordinary skill in the art would use additional nitrogen source for the method.

It is acknowledged that the amount of nitrogen provided by vitamin B complex present in the milled rice would be far less than that provided by amino acids or proteins of white rice (unmilled rice). However, this does not conclude that the amount is not sufficient for microorganisms to use vitamin B complex as a source for nitrogen. While it may not be sufficient in certain conditions, however, it can be a source for nitrogen.

Furthermore, fermentation can be carried out by certain microbes without additional nutrients. Javanainen et al. teach lactic acid fermentation can be carried out from barley flour without additional nitrogen source, vitamins or minerals (see entire document). This teaching suggests that fermentation of non-nitrogen containing product can be carried out without nitrogen sources. Thus, not only the presence of vitamin B complex in milled rice as taught by Shaw et al. can be a source for nitrogen, but also nitrogen is not necessarily required for the growth of microorganisms and production of non-nitrogen containing products of fermentation.

A prior art reference that “teaches away” from the claimed invention is a significant factor to be considered in determining obviousness; however, “the nature of the teaching is highly relevant and must be weighed in substance. A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.” In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir.

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1994) (Claims were directed to an epoxy resin based printed circuit material. A prior art reference disclosed a polyester-imide resin based printed circuit material, and taught that although epoxy resin based materials have acceptable stability and some degree of flexibility, they are inferior to polyester-imide resin based materials. The court held the claims would have been obvious over the prior art because the reference taught epoxy resin based material was useful for applicant's purpose, applicant did not distinguish the claimed epoxy from the prior art epoxy, and applicant asserted no discovery beyond what was known to the art.).

While lack of nitrogen source can produce less optimal condition for microorganism growth, however, based on the prior art that lactic acid fermentation from starch source (i.e. barley flour) can be done without additional source of nitrogen, even if the efficiency is inferior, it does not teach away to directly use the glucose rich syrup for fermentation as it is without additional nitrogen source.

It is recommended that applicant provides unexpected and surprising results by using the glucose-rich syrup as is for the growth of microorganism to produce a fermentation product.

***Claim Rejections - 35 USC § 112 (New Rejection)***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-16, 18-20, 31-36 and 53-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for producing non-nitrogen containing fermentation product, does not reasonably provide enablement for nitrogen containing fermentation product such as amino acids. The specification does not enable any person skilled

in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The current invention is directed to a method of producing fermentation products by growing a microorganism in the glucose-rich syrup as is without any additional nutrients.

The specification discloses at p.4, lines 9-12:

"For example, the glucose-rich syrup prepared from rice can be used to produce rice wine directly or can also be mixed with grapes to facilitate the production of red wine. To produce amino acids, one or more nitrogen sources should be present in the glucose-rich syrup. For example, one can add urea to the glucose-rich syrup."

The specification clearly discloses that to produce amino acids, one or more nitrogen sources should be present. Therefore, while non-nitrogen containing fermentation products may be produced by directly using the glucose-rich syrup, it is considered not enabled for nitrogen-containing fermentation product such as amino acids.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-16, 18-20, 31-36, 45, 47, 48 and 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw et al. (of record) in view of Seidman et al. (of record) in further view of Jones et al. (of record), Nutrition Facts on glutinous rice (of record), Javanainen et al. (1995, Biotechnology Techniques) and Skory et al. (of record).

Shaw et al. teach a method of converting milled rice to high-maltose syrup from milled

rice (rice flour) in water forming slurry, followed by liquefaction with  $\alpha$ -amylase, and heating to the temperature to the point of  $\alpha$ -amylase denaturation where all the proteins in the rice flour being essentially heat-coagulated, and removed by centrifugation, and the resulting supernatant was further treated with  $\beta$ -amylase and debranching enzymes to produce the high-maltose syrup (p.1071, under Results and Discussion; Fig. 1).

Although Shaw et al. disclose that autoclaving step up to the temperature of 128°C would carry out liquefaction by thermostable  $\alpha$ -amylase and at the same time protein coagulation is performed, which allows easier removal of proteins, Shaw et al. do not particularly teach the temperature used for coagulating protein being 90°C.

However, it is well known in the art that the coagulating temperatures for two globulins present in rice are 74 and 90°C (p.416).

Therefore, it would have been obvious to a person of ordinary skill in the art to use higher temperature (i.e. 90°C) to obtain both of globulins present in rice coagulated in the method of Shaw et al.

The person of ordinary skill in the art would have had a reasonable expectation of success in using the temperature of 90°C for the  $\alpha$ -amylase liquefaction step of Shaw et al. carrying out heat-coagulation of rice proteins at the same time.

Shaw et al. do not teach the use of a hydrolyzing enzyme that hydrolyzes starch or oligosaccharide to glucose.

Seidman et al. teach a process of liquefying starch derived from rice, tapioca, sorghum, potatoes, etc. (see column 5, lines 6-10) to a soluble hydrolysate using thermostable  $\alpha$ -amylase at a temperature about 170°F-195°F, which is 76.7°C-90.5°C (see column 2, lines 46-60), and then

a saccharification enzyme such as glucoamylase in the second step (see column 2, lines 8-12).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to try glucoamylase which is used in the second step of Seidman's method to replace  $\beta$ -amylase and debranching enzymes of Shaw et al. to form glucose-rich syrup in the method of Shaw et al.

The skilled artisan would have been motivated to make such a modification because glucose-rich syrup has commonly used for various different industrial purposes including production of fermented products, and also for food industry, and a person of ordinary skill in the art would recognize the method of Shaw et al. can be modified to generate glucose-rich syrup from rice by simply using glucoamylases taught by Seidman et al.

Shaw et al. in view of Seidman et al. do not teach the use of glucose-rich syrup as is for growing a microorganism to produce a fermentation product.

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use the glucose-rich syrup of Shaw et al. in view of Sediman et al. for fermentation process.

This is because it is well known in the art that glucose derived from rice is a source for fermenting rice wine with yeast or any other ethanologenic microorganisms (e.g. filamentous fungi), and a person of ordinary skill in the art would recognize that the glucose-rich syrup of Shaw et al. in view of Seidman et al. does not require any additional nutrients since rice contains vitamins (particularly, vitamin B such as riboflavin, niacin, folate, thiamin) and phosphorus according to the Nutrition Facts of glutinous white rice (see the table). Furthermore, even though the process removes proteins from rice, which can be source of nitrogen (i.e. amino

acids), these vitamin B complex can be also nitrogen sources for microorganisms. Thus, the glucose-rich syrup produced by the method of Shaw et al. in view of Seidman et al. can be used for fermentation (growth of microorganisms) directly without further addition of other nutrients.

Still further, as taught by Javanainen et al., it is possible to ferment non-nitrogen containing product from starch sources without additional nitrogen sources. Thus, it would have been obvious to a person of ordinary skill in the art to try fermentation of glucose-rich syrup of Shaw et al. without additional nitrogen sources. This is because a person of ordinary skill in the art would recognize a benefit of using minimal preprocessing and/or supplementation based on the teaching of Javanainen et al. (see Introduction). Thus, a person of ordinary skill in the art would try not to use additional supplements including nitrogen sources since it is known in the art that fermentation for non-nitrogen containing product can be carried out without a nitrogen source as taught by Javanainen et al.

Shaw et al. in view of Seidman et al. do not teach the step for producing ethanol by fermentation with *Aspergillus oryzae* for 3 or 5 days (claims 45-50).

Skory et al. teach a fermentation process of simple sugars (glucose) using *Aspergillus oryzae* to produce ethanol (fermentation product) (see Table 1), and Skory et al. also show various duration of fermentation including 3-5 days and the yield of ethanol (see Fig.1).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to try to use *Aspergillus oryzae* to ferment the glucose-rich syrup of Shaw et al. in view of Seidman et al. to produce fermentation product because it is well known in the art that *Aspergillus oryzae* is one of commonly used fungi in fermentation art.

The Supreme Court recently states in KSR v. Teleflex (550 US82 USPQ2d 1385, 2007)

"The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." Id., at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103." See also M.P.E.P. §2141.

With regard to the limitation directed to the glucose concentration being 105 mg/ml or 114 mg/ml, and the limitation directed to the yield of ethanol being 10.5% or 13.5%, Shaw et al. in view of Seidman et al. in further view of Skory et al. do not particularly teach the limitations.

The limitations are directed to the results obtainable from the method claimed in the current application. The limitations do not require any process step to be carried out other than disclosed in the current claims. Thus, the limitation does not limit the method of the current invention. However, since the method steps of Shaw et al. in view of Seidman et al. in further view of Skory et al. is substantially similar, if not identical, the results obtainable from the methods of Shaw et al. in view of Seidman et al. in further view of Skory et al. is expected to be substantially the same as the claimed invention.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

### ***Conclusion***

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/  
Primary Examiner, Art Unit 1651